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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,367

04/12/2004

David R. Walt

21629-003CON

4841

30623

7590

04/30/2008

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C  
ATTN: PATENT INTAKE CUSTOMER NO. 30623  
ONE FINANCIAL CENTER  
BOSTON, MA 02111

EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

04/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/823,367	<b>Applicant(s)</b> WALT ET AL.	
	<b>Examiner</b> Eric E. Silverman, PhD	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 29-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-28, 61 and 62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' response, filed 3/11/2008, has been received. Claims 1 – 62 are pending, and claims 1 – 22 and 29 – 60 have been withdrawn as directed to non-elected subject matter.

Claims 23 – 28, 60, and 61 are treated on the merits in this action.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23 – 28, 61 and 62 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,627,314 to Matyjaszewski ("Maty") in view of US 5,820,884 to Milstein for reasons of record and those discussed below.

#### ***Response to Arguments***

Applicants' arguments have been fully considered, but are not persuasive. Applicants' first argue that the artisan looking to modify Maty would not look to the Milstein reference, because the two use different chemistries to produce their respective particles. This argument is not well understood. To the extent that Applicants are alleging that the two references are not combinable because they are directed to different fields of art, it is noted that both references are in fact related to the same field of endeavor. Specifically, both references are directed to particles that have potential application in drug delivery. See col. 3, lines 41 – 53 of Maty, and the abstract of

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Milstein. One of ordinary skill in the art would have been motivated to consider all the related art in the field of particulate drug delivery when endeavoring in this field and applicant's argument about different chemistries to produce the particles is unclear as to why this would be a different field art.

Applicants next argue that because of the known fact that the surface density of reactive groups on a particle surface decreases as the particle size increases, the artisan would expect to have difficulty forming a polymer shell that completely coated the core if the cores of Maty were increased in size as motivated by Milstein. Applicant also avers that this problem would be exacerbated if all of the initiators did not actually initiate. The response to this argument is two-fold.

1) The instant claims do not require that the polymer shell completely cover the core. Indeed, the claims have no limitations regarding the extent of coverage, or density of polymer chains, that must be provided on the core. Applicants' implicitly agree that the artisan would expect to be able to provide some core coverage by polymers, even if that coverage were incomplete. Such incomplete coverage, or a shell that partially but not completely surrounds the core, still reads on the instant claims.

2) Even if, for the sake of argument, the claims were amended to require that the core be completely or near-completely covered by polymer chains, the argument would still not be persuasive. At the time of the invention, the level of skill in the art of manipulating the surface chemistry of microparticles was fairly high; the artisan would have expected to make the required manipulations with a reasonable expectation of success irrespective of the density of the surface-groups. For an idea of the level of

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skill in the art of modifying microparticles, see the following US patents, which provide a non-exhaustive list of the variety of manipulations known to the artisan. 4,150,714 (modification with organometallics), 4,522,958 (modification of silica microparticle by alcohol hydrolysis), 5,378,405 (modification with ionically conducting polymers), 5,015,695 (carboxylate modified microparticle surfaces), 5,543,158 (attachment of PEG to surfaces), and 5,814,407 (modification of silica microparticles to give hydroxyl groups on the surface). Because the skill level in the art is quite high, the artisan would expect to readily overcome any problems associated with a lower surface density of reactive groups. Furthermore, in an ATRP system, it is understood that essentially all of the initiators initiate polymerization, wherein the initiation step occurs at a very rapid rate as compared to the propagation, chain transfer, or termination steps. Indeed, it is this rapid and complete initiation that gives ATRP its signature qualities, a low polydispersity index and high degree of control of the molecular weight of the polymer product. Without rapid and complete initiation, the molecular weight could not be controlled, nor would the polydispersity index be low. Indeed, it is clear from the GPC data in Maty that the polydispersity index ( $M_w/M_n$ ) is low, indicating that the initiators do indeed act as expected (see Fig. 7 of Maty). Incomplete initiation is therefore not expected to be an issue when ATRP initiators (such the 2-bromoisobutyryl in Maty) are used.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman, PhD

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